

Docket No. CV0275

REMARKS

This Amendment and these remarks are being filed in response to the Official Action mailed in this application on July 1, 2009. A request for a one-month extension of time and a Notice of Appeal accompany this response. When this amendment is entered, claims 9-11 and 13-16 will be pending in the application. Entry of this amendment and reconsideration of this application are respectfully requested.

Claims 1 and 9-16 were rejected under 35 U.S.C. §112, first paragraph. Applicants respectfully traverse this rejection.

According to the rejection, Applicants' recitation of vertical wicking 'perpendicular to the plane of the dressing' in instant claims 1, 13 and 15 presents new matter. Further, according to the rejection, the passages referred to by Applicants only discuss 'vertical wicking of wound exudate away from the wound'; there is no reference point addressing the particular direction based on the vertical wicking property; and there is no definition provided that would support Applicants' limitation 'perpendicular to the plane of the dressing' as now claimed. Applicants disagree.

Nevertheless, in order to place the application into condition for allowance or at least to reduce the issues on appeal, Applicants have removed the language.

For these reasons, Applicants submit that the rejection has been obviated.

Next, claims 1 and 9-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 3,842,996 (hereafter "Carlisle") in view of U.S. Patent No. 5,899,893 (hereafter "Dyer, et al.") and further in view of U.S. Patent No. 5,124,197 (hereafter "Bernardin, et al."). Applicants respectfully traverse this rejection.

The present invention is concerned with a method of treating an acute wound using a wound dressing (as a substitute for a biological dressing or skin graft) wherein the wound dressing comprises highly absorbent fibers.

Applicants have found that by the use of absorbent fibers in the above method, fibrous dressings can be used as substitutes for biological dressings. Biological dressings are sophisticated and, therefore, tend to be expensive and carry the same risks of cross-contamination that are encountered with blood and blood products. The advantages of the new method embodied in Applicants' claims include that the

Docket No. CV0275

dressings can be used as a substitute for a biological dressing at lower cost and without the risk of contamination.

Carlisle, on the other hand, is concerned with pressure dressings. According to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting (column 6, lines 36 to 37). Carlisle does not, therefore, consider his dressing as a substitute for a biological dressing, but rather as a preparation for it. Carlisle would not, therefore, motivate the person of ordinary skill in the art to use a fibrous dressing as a substitute for a biological dressing.

Further, dressings of Carlisle are dense, laminar dressings that wick laterally and bar the movement of exudate into the dressing (column 3, lines 17-20). In use, the dressings of Carlisle are placed on the wound and, at dressing change time, the dressings are removed by delaminating or soaking or providing the dressings with a wound contact layer that has the property of release from the wound. Dressing changes occur every 12 hours or so. Carlisle does not, therefore, suggest that the dressings can be used in the manner of a biological dressing and as claimed herein which is left in place in its entirety and undisturbed until the wound has healed. The differences between the method and dressing characteristics of Carlisle compared to Applicants' invention are shown particularly in the wording of Claim 13. Claim 13 has the method steps of: allowing the dressing to become adhered to the wound; leaving the dressing in place until it dries out to form a crust; and removing the dressing once the wound has healed. Carlisle does not disclose these steps and does not suggest them. Carlisle also does not teach that the dressing is left in place, or vertical wicking into the dressing, both as required by Applicants' claims. In contrast, Carlisle discloses changing of the dressing, and only lateral wicking, and Carlisle does not suggest that there would be any advantage in vertical wicking into the dressing.

Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds as claimed, the dressing adheres to the wound. (See page 5, second paragraph). This type of behavior would usually only be seen with a biological dressing such as allograft, and it is a truly surprising discovery by the Applicants. It is illustrated particularly in Example 1, where it is described that the wound dressing dried out to form a crust as wound healing was in progress, and the

Docket No. CV0275

dressings remained in place for 14 days. This method of use is very different from that contemplated in Carlisle where the emphasis is on the dressing being changed.

According to the action, the limitation "for a period of time until after epithelial outgrowth and vertical wicking into the dressing occur" fails to set forth any specific time or duration parameters. Applicants disagree. Certainly, depending on many factors, the amount of wound exudate and time to healing of a wound will vary. The claim language accounts for this variation. Nevertheless, Applicants have also amended the claims to remove the "time" concern.

The action then relies on Dyer, et al. to supply the deficiencies of Carlisle regarding the amount of water absorbed by the dressings. However, there is no suggestion in Carlisle to do so. While the Examiner argues at page 5 of the action that there is motivation to combine Dyer, et al. and Carlisle to obtain a wound dressing that imparts vertical wicking, Applicants see no motivation for at least two reasons. First, Carlisle is concerned with pressure dressings. The dressings have a deep lamellar structure to give a highly dense dressing that is able to transmit pressure to the wound. For this reason, Carlisle selects its dressing materials carefully and specifically recites in claim 1 that the dressing should have limited compressibility. The limited compressibility means that the tape used to adhere the dressing to the wound can increase pressure application to the wound (column 1, lines 59-65). The dressing material of Dyer, et al., is a foam. It is well known that foams are highly compressible. A person having ordinary skill in the art would not, therefore, substitute the foam of Dyer, et al. for the lamellar dressing of Carlisle in order to improve the Carlisle dressing as the combination would mean that the Carlisle dressing no longer functioned as a pressure dressing. Second, neither Dyer, et al., nor Carlisle disclose vertical wicking into the dressing or that the property would have an advantage when used in a dressing on an acute wound.

It is also implied on page 5 in the action that the amount of water absorbed by the dressings in Applicants' claims is nothing more than a difference in concentration. This treats Applicants' claims as though they related to a composition with different optimum ranges from a known composition. Clearly, that is not the case.

Docket No. CV0275

Next, the action relies on Bernardin, et al. for teaching absorbent webs of fibers with vertical wicking. However, it is clear from Bernardin, et al. that the expression "vertical wicking" is being used in the same manner as it is used in Dyer, et al. "Vertical wicking" is being used in Bernardin, et al. as the wicking of a vertically held strip of a test material against gravity. In relation to the wound, this wicking would be lateral, not into the dressing. See column 8, lines 1-22, of Bernardin, et al. Thus, Bernardin, et al. does not teach vertical wicking into the dressing in the same sense as it is used in Applicants' claims. (Similarly, the wicking in Dyer, et al. is the wicking of a vertically held strip of a test material against gravity. See column 4, lines 9 to 11, column 7, lines 41 to 43 and column 24, line 63, through column 26, line 2 of Dyer, et al.). There is no disclosure of vertical wicking into the dressing in Bernardin, et al. (or in Dyer, et al.), nor is there a disclosure that the property of vertical wicking into the dressing could be of an advantage when used to treat acute wounds.

According to the rejection, Applicants have not demonstrated any unexpected or superior results through the use of their wound dressing method steps over that of the prior art. Applicants again disagree. Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds, the dressing adheres to the wound and forms a crust. This type of behavior would usually only be seen with a biological dressing such as allograft, and it is a truly surprising discovery. Specifically, page 3 of the specification reads as follows:

Docket No. CV0275

We have found that a wound dressing, to be suitable as a substitute for a biological dressing preferably is adherent to the wound without preventing the outgrowth of the epithelium. This is truly surprising since conventional wisdom teaches that wound dressings should not adhere to the acute wound and many known dressings are provided with measures to avoid adherence such as being impregnated with paraffin or being coated with silicone. We have found that an adherent dressing has advantages over the prior art dressings which allow the dressing to be used in those situations where a biological dressing would otherwise be used.

We have also found that wound dressings suitable as replacements for biological dressings preferably promote the migration of enzymes, neutrophils, fibroblasts and cellular debris into the dressing. Whilst not wishing to be bound by theory we believe that this migration, which we term as "vertical wicking", modulates the inflammatory response of the wound and contributes to successful healing of the wound.

That the dressing adheres to the wound and acts like a biological dressing when it is not one is an unexpected result. Applicants believe that this is due to the modulation of the inflammatory response caused by the vertical wicking property of the dressing. The assertion in the rejection is therefore clearly incorrect.

The unexpected results of vertical wicking into the dressing are also shown in the Examples where, in Example 1, dressings used in the method of the invention adhere to the wound in the same manner as allograft skin. Applicants' claims recite that in the method, the dressing becomes adhered to the wound which again is a feature of biological dressings and is a property that is avoided by known wound dressings. In Example 2, the adherent properties of dressings according to the invention are described again and the evidence of vertical wicking into the dressing is given. In Example 3, the method of the invention is used to provide a temporary cover to excised

Docket No. CV0275

skin. The description points to several unexpected results which are attributed to vertical wicking into the dressing. Accordingly, the rejection is therefore incorrect that that there are no unexpected results

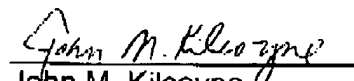
It was also argued in a previous rejection that although the dressing of Carlisle must be saturated or provided with a wound contact layer to be removed, this does not impart patentability to the claims. However, Applicants made mention of this difference in method because Carlisle obviously removes the dressing before healing is complete unlike Applicants' method. Contrast Carlisle's saturating and wound contact layer and the method steps these imply with steps c) and d) of claim 13.

The inventors of the present invention discovered that it is possible to treat burns by the use of a fibrous dressing that is able to wick vertically into the dressing and becomes adhered to the wound. This behavior is truly surprising. Neither Carlisle, nor Dyer, et al., nor Bernardin, et al. mention vertical wicking into the dressing as it is used herein, or that vertical wicking into the dressing could be an advantage in a dressing used to treat acute wounds. Neither Carlisle, nor Dyer, et al., nor Bernardin, et al. disclose the method of treating an acute wound with a dressing that vertically wicks into the dressing or that is left in place as has been claimed by Applicants. No combination of the teachings of Carlisle, Dyer, et al., and Bernardin, et al. suggest the claimed methods. For these reasons, Applicants believe that the claims are patentable over the cited documents.

For all these reasons, withdrawal of the rejections, favorable reconsideration of this application, and allowance of the pending claims, are all earnestly solicited.

Respectfully submitted,

ConvaTec Inc.
Patent Department
100 Headquarters Park Drive
Skillman, NJ 08558


John M. Kilcoyne
Attorney for Applicants
Reg. No. 33,100
(908) 904-2372

Date: November 2, 2009